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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/455,683 05/31/95 BELL

G ARCD:177/WIM

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HM22/0130

EXAMINER

LANDSMAN, R

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

08/455,683

Applicant(s)

BELL ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64 and 91-136 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91-96 is/are allowed.
- 6) ☒ Claim(s) 97-136 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *1. Formal Matters*

- A. Amendment F, filed 11/14/00, has been entered into the record.
- B. Claims 47-52, 59, 63-67 and 81-114 were pending in the application. Claims 47-52, 59, 63, 65-67 and 81-90 have been cancelled and new claims 115-136 have been added. It appears from the amendment of Paper No. 29 that claim 64 has been cancelled. However, the Examiner has not been able to find the amendment which cancelled this claim. Therefore, claims 64 will be considered pending. Claims 64 and 91-136 are currently pending in the application.
- C. All 35 USC Statutes not cited in this Office Action can be found, cited in full, in a previous Office Action.

## Withdrawn Objections

- A. The objection to the specification, as stated in the 35 USC 112, first paragraph rejection on page 5 of the Office Action dated 8/10/00 has been withdrawn because Applicants have demonstrated that the protein of SEQ ID NO:12, which is encoded for by SEQ ID NO:11, which is a partial DNA sequence of a human kappa opioid receptor, has utility, such as in the production of chimeric proteins.

## Withdrawn Rejections

### *1. Claim Rejections - 35 USC § 101*

- A. The rejection of all claims under 35 USC 101 have been withdrawn because Applicants have demonstrated that the protein of SEQ ID NO:12, which is encoded for by SEQ ID NO:11, which is a partial DNA sequence of a human kappa opioid receptor, has utility, such as in the production of chimeric proteins.

***2. Claim Rejections - 35 USC § 112, second paragraph***

- A. The rejection of all claims under 35 USC 112, second paragraph has been withdrawn since it would be clear to one of ordinary skill in the art how to determine that the test compound is an agonist.

**Maintained Objections**

- A. Claim 64 remains rejected for the reasons already of record in the Office Action dated 8/10/00.

**Maintained Rejections**

***1. Claim Rejections - 35 USC § 112, first paragraph – lack of written description***

- A. Claims 97 and 109 and their dependent claims, 98-102, 110-114 remain rejected under 35 USC 112, first paragraph and new claims 115-121 and 123-129 are also rejected for the reasons already of record on page 6 of the Office Action dated 8/10/00 since they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants were unsure whether this rejection was an enablement or a written description rejection. The Examiner is stating that this is a written description rejection. Applicants argue that the specification provides sufficient guidance and working examples of less than full-length opioid receptors and indicates the coding sequence of SEQ ID NO:11.

First, while the specification does give adequate support for less than full-length opioid receptors, such as the claimed chimeras, it provides no written description for the full-length receptor encoded for by SEQ ID NO:11, since SEQ ID NO:11 does not encode the full-length open reading frame of a human kappa opioid receptor. Therefore, the claims which read, for example, "at least 30 nucleotides of SEQ ID NO:11" would read on the nucleic acid molecule encoding the full-length opioid receptor which Applicants were not in possession of at the time of the filing of this application. However, if Applicants

amended the claims to recite the limitation that the nucleotide molecule be no larger than SEQ ID NO:11, so as to not read on the full-length receptor encoded for by SEQ ID NO:11, this rejection will be withdrawn.

Applicants can overcome this rejection by amending the claims in two ways:

- (a) claims 97-102, 109-121 and 123-129 need to recite, for example, "...a nucleic acid sequence comprising a heterologous insert consisting of 30 contiguous bases or more of SEQ ID NO:11..."
- (b) claim 121 needs to be separated into two claims. The first claim reciting SEQ ID NO:2 is fine since SEQ ID NO:2 is a full-length receptor. However, the next claim needs to recite "...polypeptide consisting of SEQ ID NO:12" since this is not a full-length open reading frame.

*2. Claim Rejections - 35 USC § 112, first paragraph - scope*

- A. Claims 91-102 and 109-114 remain rejected under 35 USC 112, first paragraph and new claims 115-136 are also rejected for the reasons already of record on page 8 of the Office Action dated 8/10/00. Applicants are not enabled for all molecules which are able to "interact with" an opioid receptor. This rejection can be overcome by replacing the phrase "to interact with" with "to specifically bind to."
- B. Claims 103-114 and 129-135 (part (a)(1) of claim 129) remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 7 of the Office Action dated 8/10/00. Applicants have stated that the second extracellular loop is necessary for agonist interaction with the claimed opioid receptors, but have not recited this limitation in the claims. This rejection could be overcome if Applicants amend the claims to recite the amino acid residue numbers of the second extracellular loop.

### Conclusion

A. Claims 91-96 are allowable

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### *Advisory information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
January 29, 2001

*Gary L. Kunz*  
**GARY L. KUNZ**  
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